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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,111

10/12/2004

Koji Oida

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04/07/2008

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,111	<b>Applicant(s)</b> OIDA, KOJI	
	<b>Examiner</b> Brian-Yong S. Kwon	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) 7-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Applicants Response to Restriction Requirement Acknowledged***

1. Applicants election with the Group I, claims 1 and 2, along with (+)-(3R, 5S, 6E)-7-[2-cyclopropyl-4-(4-fluorophenyl)-3-quinoliny]-3,5-dihydroxy-6-heptenoic acid or its salt as the elected species is acknowledged. Claims 7-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

Because applicant did not specifically traverse the restriction requirement, the election has been treated as an election without traverse.

### ***Priority***

2. Receipt is acknowledged of papers, JP 2002-111247 filed 04/12/2002, submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Undas et al.

(Circulation, May 8 2001, Vol. 103, pp. 2248-2253).

Undas discloses HMG-CoA reductase inhibitor (e.g., simvastatin) as antithrombotic agent (abstract; Discussion).

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bocan (WO 97/16184).

Bocan teaches a composition comprising ACAT inhibitor and HMG-CoA-reductase inhibitor (e.g., lovastatin, simvastatin, pravastatin, fluvastatin, rivastatin, atorvastatin, etc...) that is useful in lowering cholesterol, decreasing the adherent properties of the blood vessels and decreasing the coagulation of platelets (abstract; page 1, lines 9-18; page 3, lines 4-5; page 3, line 21 through page 5, line 4; claims).

Since the interpretation of the instant claims reciting open transitional language “comprising” allows for the inclusion of any other unspecified ingredients even in major amounts in said composition, the referenced composition anticipates the instant invention.

5. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Muramatsu et al. (WO 97/23200).

Muramatsu teaches a composition comprising the claimed (+)-(3R, 5S, 6E)-7-[2-cyclopropyl-4-(4-fluorophenyl)-3-quinoliny]-3,5-dihydroxy-6-heptenoic acid (pitavastatin or NK-104) or its salt (abstract; page 2, lines 9-28; Examples; claims).

Although Muramatsu is silent about the functional characteristic of said compound in promoting thrombomodulin expression or expressing anticoagulant activity, such activity deems to be inherent to the referenced composition. Claims to a composition possessing a particular property or characteristics are still properly rejected by a reference to the same composition,

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even if the reference does not address or acknowledge the property. The property or characteristic is deemed to be inherent to the composition, i.e., it was always there.

### Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/  
Primary Examiner, Art Unit 1614